

In the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

List of claims:

Claim 1 (Original): A method for the prophylaxis or treatment of infection by a microorganism in a biological environment from where the microorganism acquires iron, heme or porphyrin said method comprising administering to said environment an effective amount of an agent for a time and under conditions sufficient to antagonize the interaction between a molecule derived from said microorganism having an HA2 domain and an HA2-binding motif on a porphyrin containing molecule present in said biological environment.

Claim 2 (Original): A method according to Claim 1 wherein the microorganism is *Porphyromonas gingivalis* or a related microorganism.

Claim 3 (Previously Presented): A method according to claim 1 wherein the biological environment is a mammal or reptile or insect or bird or species of fish.

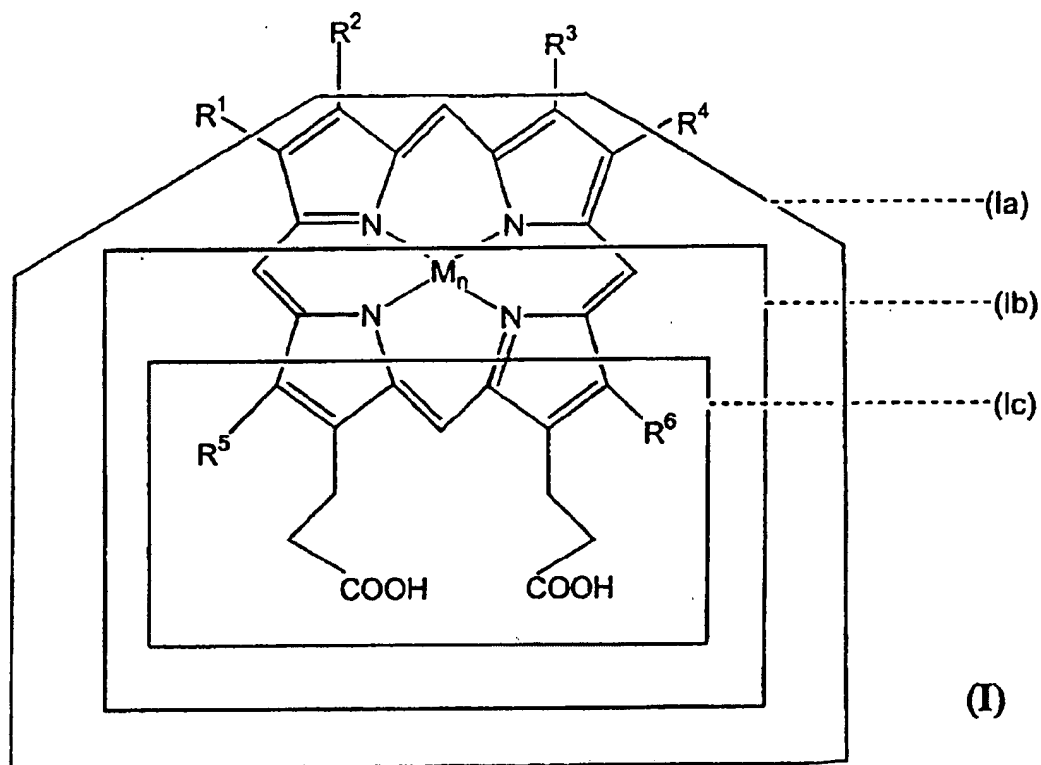
Claim 4 (Original): A method according to Claim 3 wherein the mammal is a primate, human, livestock animal or a companion animal.

Claim 5 (Original): A method according to any one of Claims 1 to 4 when used for the treatment of a disease condition in the oral cavity, nasopharynx, oropharynx, vagina or urethra or other vascular or mucosal regions or cavities or in the hooves of livestock animals.

Claim 6 (Previously Presented): A method according to any one of Claims 1 to 4 wherein the HA2-containing molecule is a gingipain, an hagA gene product or a TonB-dependent protein such as but not limited to Tla protein or a homologue thereof.

Claim 7 (Previously Presented): A method according to Claim 1 wherein the porphyrin moiety is a heme.

Claim 8 (Original): A method according to Claim 7 wherein the HA2-binding motif comprises a region comprising or within substructure (Ic) of structure (I):



wherein R₁ and R₆ are the same or different and each is an alkyl such as a methyl, ethyl or propyl group, or hydrogen, hydroxyl, carboxyl, aldehyde, acetaldehyde or keto group, M is a metal ion in various oxidation states such as but not limited to Fe, Fe⁺⁺ and Fe⁺⁺⁺ and is optionally present such that n is 0 or 1 or a structurally or functional homologue thereof.

Claim 9 (Original): A method for the prophylaxis or treatment of infection by a microorganism in a mammal, said microorganism substantially requiring exogenous iron, heme or porphyrin for growth or maintenance wherein said method comprises administering to said mammal an effective amount of an agent for a time and under conditions sufficient to antagonize the interaction between a molecule derived from said microorganism and having an HA2 domain and an HA2-binding moiety on a porphyrin-containing molecule such as but not limited to hemoglobin or a precursor form thereof or part thereof such as heme and wherein said HA2 domain comprises:

- (i) an amino acid sequence substantially encoded by the nucleotide sequence set forth in <400>5 or a nucleotide sequence having at least about 40% similarity thereto or capable of hybridizing thereto under low stringency conditions; and/or
- (ii) an amino acid sequence substantially as set forth in <400>6 or an amino acid sequence having at least about 40% similarity thereto or at least about 20% identity after optimum alignment with same sequence.;

wherein said amino acid sequence is capable of interacting with an HA2-binding moiety on a porphyrin-containing molecule such as but not limited to hemoglobin or a precursor form thereof or part thereof such as heme.

Claim 10 (Original): A method for prophylaxis or treatment of peridontal, pulmonary, vaginal, urethral or hoof disease resulting from infection by *P. gingivalis* or related microorganism in a mammal said method comprising administering to said mammal an effective amount of a agent for a time and under conditions sufficient to antagonize the interaction between a *P. gingivalis*-derived molecule having an HA2 domain and an HA2-binding motif on hemoglobin.

Claim 11 (Previously Presented): A method for the prophylaxis or treatment of *P. gingivalis* infection or infection by a related microorganism in a mammal, said method comprising administering to said mammal an effective amount of an agent for a time and under conditions

sufficient to antagonize the interaction between a *P. gingivalis*-derived HA2-containing molecule comprising the amino acid sequence ALNPDNYLISKDVTG <400>1 or ALNPDNYLISKDVTGATKVKY <400>8 or an amino acid sequence having at least 40% similarity to <400>1 or <400>8 or at least about 20% identity after optimum alignment with same sequence or an amino acid sequence encoded by the nucleotide sequence <400>7 or a nucleotide sequence having at least 40% similarity thereto or a nucleotide sequence capable of hybridizing thereto under low stringency conditions and an HA2-binding motif comprising and including propionic acid groups or anionic or salt forms thereof such as but not limited to the region defined by substructure (Ic) in Formula (I) on a porphyrin-containing molecule such as but not limited to hemoglobin or a precursor form thereof or part thereof such as heme.

Claim 12 (Withdrawn): An agent capable of antagonizing interaction between an HA2-containing molecule and an HA2-binding motif on a porphyrin-containing molecule such as but not limited to hemoglobin or a precursor form thereof or part thereof such as heme.

Claim 13 (Withdrawn): An agent according to Claim 12 wherein the porphyrin is heme.

Claim 14 (Withdrawn): An agent according to Claim 12 or 13 wherein said agent comprises propionic groups in planar alignment with respect to the molecular structure of said agent.

Claim 15 (Withdrawn): Use of a gingipain or an HA2 domain containing part thereof or an HA2-containing molecule in the manufacture of a medicament for the prevention or treatment of *P. gingivalis* infection or infection by a related microorganism.

Claim 16 (Withdrawn): Use of an antagonist of *P. gingivalis*-derived HA2-containing molecule interaction with a porphyrin-containing molecule such as but not limited to hemoglobin or a precursor form thereof or part thereof such as heme in the manufacture of a medicament for the prophylaxis or treatment of *P. gingivalis* infection or infection by a related microorganism.

Claim 17 (Withdrawn): A therapeutic composition comprising an agent according to Claim 12 or 13 and one or more pharmaceutically acceptable carriers and/or diluents.

Claim 18 (Previously Presented): A method according to claim 5 wherein the HA2-containing molecule is a gingipain, an hagA gene product or a TonB-dependent protein such as but not limited to Tla protein or a homologue thereof.

Claim 19 (Previously Presented): A method according to claim 6 wherein the porphyrin moiety is a heme.

Claim 20 (Withdrawn): A therapeutic composition comprising an agent according to claim 14 and one or more pharmaceutically acceptable carriers and/or diluents.

REQUEST FOR RECONSIDERATION OF THE FINALITY OF OFFICE ACTION

Applicants assert that the finality of the Office Action is premature since grounds for rejection were not previously set out in any Office Action.

In prior Office Actions, a Restriction Requirement was mailed February 7, 2003 which was responded to on May 7, 2003. A Notice to Comply from Examiner Laurie Mayes was mailed by the Patent Office on July 21, 2003. The notice required an amendment to correct conflicting references to a SEQ ID NO in the specification and claims. A Response to the Notice to Comply was filed on August 14, 2003 wherein the specification and claim 11 were amended to correct the inconsistencies.

The present Office Action is the first action on the merits received by the Applicants. Applicants' attorneys have searched and have not found any other Office Actions received by applicants' attorneys in any of their offices after the Notice to Comply and prior to the present Office Action. The present Application is not a continuing application, or a substitute for, an earlier application and thus the conditions for Final Rejection on First Action are not met (*see* MPEP 706.07(b))

Accordingly, Applicants submit that the finality of the Office Action dated November 7, 2003 is improper and respectfully request withdrawal of the finality of the rejection. (*see* MPEP 706.07(d)).

Applicants have previously communicated this issue to the Examiner. In the event the request is denied, Applicants request the Examiner to notify Applicants' attorneys as soon as possible, so that Applicants can act to preserve the pendency of the application.